

RECEIVED  
CENTRAL FAX CENTER

FEB 10 2004

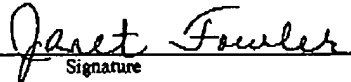
OFFICIAL

## CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

JANET FOWLER

Type or print name of person signing certification

  
Signature2/10/04  
DatePATENT APPLICATIONIN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	James A. Hoffmann	)	Confirmation No. 4243
Serial No.	:	10/072,540	)	
Filed	:	February 8, 2002	)	Group Art Unit:1614
For	:	GLP-1 Formulations	)	Examiner: Delacroix-Muirheid
Docket No.	:	X-11368A	)	

RESPONSE TO RESTRICTION AND/OR ELECTION REQUIREMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

An Election Requirement was set forth in an Office Action mailed January 14, 2004, for the patent application captioned above.

Applicant submitted new claims 35-53 in a preliminary amendment dated February 8, 2002. Applicant inadvertently cancelled claims 24-34. Applicant agrees with the Examiner that these claims, 24-34, are not present in this application. Please cancel claims 1-23. Thus, claims 35-53 are the only pending claims in the present application.

Applicant also inadvertently requested priority to AN 09/573,809. Please disregard this priority request. Applicant intended to request priority to the parent case, AN 09/585,181, which WAS filed on June 1, 2000. Therefore, on page 1, lines 5-7, replace:

This application is a continuation of International Application Serial No. PCT/US98/25515, filed December 2, 1998, which claims the benefit of U.S. Provisional Application 60/067,600, filed December 5, 1997. The entire teachings of these applications are incorporated herein by reference.

BEST AVAILABLE COPY

Serial No. 10/072,540

with:

This application is a continuation of co-pending U.S. Serial No. 09/585,181, now U.S. Patent No. 6,358,924, filed June 1, 2000.

The Examiner has grouped claims 1-10 into Group I, claims 11-23, and 53 into Group II, and claims 35-52 into Group III. Applicant has cancelled claims 1-23, therefore the only restriction that remains is between Group II (claim 53) and Group III (claims 35-52). Applicant elects Group III with traverse. Applicant respectfully disagrees with the Examiner in that the method can be practiced with a materially different product such as sulfonylurea compounds or insulin therapy. The product of the Applicant's invention is a specific stable formulation comprising a GLP-I compound. Insulin or sulfonylurea compounds in this specific formulation may not provide the same benefit to a patient. For example, it is known that insulin requires zinc to form hexamers. Applicant's formulation does not require zinc. Also, the use of sulfonylurea compounds have been linked to an increase in morbidity and mortality among patients with diabetes mellitus who suffered myocardial ischemia and infarction. Furthermore, no additional searching should be necessary beyond searching for the specific stable formulation. Applicant submits it would not be an undue burden for the examiner to additionally consider claim 53 that encompasses a method of using the specific stable formulation Application. Thus, Applicant requests that claims 35-52 be examined with claim 53.

If, for any reason, the Examiner feels that a telephone conversation would be helpful in expediting the prosecution of this case, the Examiner is urged to call me.

Respectfully submitted,



Gregory A. Cox  
Attorney for Applicants  
Registration No. 47504  
Phone: 317-277-2620

Eli Lilly and Company  
Patent Division/GAC  
Lilly Corporate Center  
Indianapolis, Indiana 46285

Feb. 10, 2004

BEST AVAILABLE COPY

Fax

*Lilly*

Eli Lilly and Company  
Lilly Corporate Centre  
Indianapolis, Indiana 46285  
U.S.A.

**RECEIVED**  
**CENTRAL FAX CENTER**

**Date: February 10, 2004**

**FEB 10 2004**

**To: Examiner Delacroix-Muirheid**  
**Company: USPTO:Commissioner for Patents**  
**Fax: 703-872-9306**  
**Phone: 703-308-2923**

**From: Greg Cox**  
**Fax: 317-276-5172**  
**Phone: 317-277-2620**  
**Total Pages: 3**

**OFFICIAL**

**Privileged and Confidential Communication**

**Subject: Response to Restriction and/or Election Requirement**  
**For 10/072,540**

**CONFIDENTIALITY NOTICE:** This fax message from Eli Lilly and Company (including all attachments) is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure, copying or distribution is strictly prohibited. If you are not the intended recipient, please contact the sender by reply fax and destroy all copies of the original message.

Please contact Jan Fowler at 317-655-1715 if you incur any difficulties with this transmission.

**BEST AVAILABLE COPY**